IN THE UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Confirmation No.: 3884

In re Application of: Charles H. Perrone Jr., et al.

Application No.: 10/771,887

Filed: February 4, 2004

Title: ROTATING/NON-

ROTATING TIBIA BASE

PLATE/INSERT SYSTEM

Art Unit: 3774

Examiner: Ann M. Schillinger

Atty. Docket No.: ZIM0587/101-451

Customer No.: 43963

APPEAL BRIEF

Mail Stop Appeal Brief Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir

In the Final Office Action dated December 23, 2010 (hereinafter the "Final Office Action"), the Examiner finally rejects claims 1-3, 6, 7, 10-16, 18, 19, 21, 22 and 24-28 of the present application. The Examiner's rejections are addressed in detail below.

This appeal follows the Notice of Appeal filed on March 23, 2011, and is accompanied by the fee set forth in 37 C.F.R. § 41.20(b)(2).

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I. REAL PARTY IN INTEREST

The real party in interest is Zimmer Technology, Inc. having its principal place of business at 150 North Wacker Drive, Suite 1200, Chicago, Illinois 60606, having rights in the present application by virtue of an assignment from the inventors recorded on June 25, 2004 at Reel 015508 / Frame 0047.

II. RELATED APPEALS AND INTERFERENCES

None of the Appellants, the Appellants' representatives, nor the assignee know of any other appeals, interferences or judicial proceedings which are related to, will directly affect or be directly affected by, or have a bearing on, the Board's decision in the pending appeal.

III. STATUS OF CLAIMS

Pending: Claims 1-3, 6, 7, 10-16, 18, 19, 21, 22 and 24-28.

Canceled: Claims 4, 5, 8, 9, 17, 20, 23 and 29-42.

Withdrawn: None.
Allowed: None.

Objected to: None.

Rejected: Claims 1-3, 6, 7, 10-16, 18, 19, 21, 22 and 24-28. Appealed: Claims 1-3, 6, 7, 10-16, 18, 19, 21, 22 and 24-28.

IV. STATUS OF AMENDMENTS

No amendments were filed after the Final Office Action of December 23, 2010.

The pending claims of the present application are provided in the attached Claims Appendix (Section IX).

V. SUMMARY OF CLAIMED SUBJECT MATTER

The following explanation of the subject matter of the present application including the subject matter defined in each of the independent claims is provided with specific reference to the

specification and the drawings as acquired by 37 C.F.R. § 41.37 (c)(v). These references are made to specific embodiments disclosed in the application and do not limit the scope of the independent claims to the specific embodiments and should not necessarily be considered to be exhaustive.

A. Background

The present invention is directed to a rotating/non-rotating tibia baseplate/insert system. The two largest and longest bones of the human body, the femur and tibia, meet at a person's knee. The head of the tibia includes two smooth concaved compartments or surfaces which articulate with the condyles of the femur. ¶ [0005]. The articulating surfaces of the natural knee may degrade and be replaced with prosthetic devices attached to the natural femur and tibia. ¶ [0006]. The tibia prosthesis typically includes a baseplate and an articulating surface or insert. ¶ [0006]. In some cases it may be desirable that the tibia insert rotate relative to the tibia baseplate. ¶ [0007]. However, in some cases it may be desirable to prevent the tibia insert from rotating relative to the tibia baseplate. ¶ [0008]. Further, it may be desirable to modify an already implanted rotating tibia insert to a non-rotating insert. ¶ [0008].

B. Independent Claim 1

i. Narrative

With the foregoing in mind, the claimed invention provides tibia baseplate 10 as illustrated in Figures 10A, 10B and 10D. Tibia baseplate 10 includes an upper surface, a lower surface, and outer perimeter side surface 33 extending between the upper surface and the lower surface as illustrated in the aforementioned figures. Insert 12 is illustrated in Figures 10A-10B. Insert 12 includes an upper surface, a lower surface, and an outer perimeter side surface 31 extending between the upper surface and the lower surface as illustrated in the aforementioned figures. Insert 12 is further adapted to be positioned above baseplate 10 as illustrated in Figure 10B. Insert 12 and baseplate 10 have a first configuration in which insert 12 is translationally fixed to baseplate 10 and rotatable relative to baseplate 10. Specifically, a connector such as cone 22 (Figure 10D) is sized to be received in opening 24 (Figure 1) to rotatably connect insert 12 to baseplate 10. ¶ [0038] Removable pin 14 can be selectively utilized to engage a portion of baseplate 10 and insert 12 to

thereby prevent rotation between insert 12 and baseplate 10. ¶ [0037]. Pin 14 is exemplified in Figures 11A-11C and 10A-10C. Pin 14 is configured to engage at least a portion of insert 12 and baseplate 10 via openings 28, 30 (Figure 10B) that are formed in the side surfaces 31, 33 (Figure 10A) of insert 12 and baseplate 10. As illustrated in Figures 11A-11C and 10B, pin 14 includes tabs 14F and 14G that are adapted to engage openings 20 and 28 (Figure 10D), respectively. Tabs 14F, 14G are sized and configured such that they may be press-fit or snap-fit with openings 20, 28 in baseplate 10 and insert 12, respectively. ¶ [0047]. Tabs 14F, 14G as well as the openings in which they are to be positioned may include a variety of configurations as detailed in ¶ [0047].

ii. Specific Language of Independent Claim 1 Including References to the Specification and Drawings

Claim 1. A device, comprising:

a first tibia base plate (10) comprising an upper surface, a lower surface and an outer perimeter side surface (33) extending between said upper surface and said lower surface of said first tibia base plate (Figures 10A, 10B, 10D) ¶ [0037];

an insert (12) comprising an upper surface, a lower surface and an outer perimeter side surface (31) extending between said upper surface and said lower surface of said insert (Figures 10A-10B), said insert adapted to be positioned above said first base plate (Figure 10B), said insert (12) and said first base plate (10) having a first configuration, wherein said insert (12) is translationally fixed to said first base plate (10) and rotatable relative to said first base plate via cone 22 and opening 24 ¶ 100381:

a connector (22) rotatably connecting said insert (12) to said first tibia base plate (10); and

at least one removable pin (14) having a first portion (14F) and a second portion (14G), said first portion (14F) of said pin sized for engagement with an opening (20) formed in said outer perimeter side surface (33) of said first base plate (10) and said second portion (14G) of said pin sized for engagement with an opening (28) formed in said outer perimeter side surface (31) of said insert (12) to thereby prevent relative rotation between said insert (12) and said first base plate (10) ¶ [0046].

C. Independent Claim 15

Narrative

Independent claim 15 includes a tibia baseplate and insert as described in the exemplifications outlined above together with a "means for rotatably connecting said insert to said first tibia baseplate." This means plus function limitation (as permitted by 35 U.S.C. §112, paragraph 6) is described in the present specification with reference to corresponding structure exemplified by cone 22 extending from insert 12 and opening 24 formed in baseplate 10. Independent claim 15 further calls for a "removable means for selective engagement with both said insert and said first tibia baseplate for preventing relative rotation between said insert and said first baseplate." This means the function limitation (as permitted by 35 U.S.C. §112, paragraph 6) is described in the present specification with reference to corresponding structure exemplified by pin 14 having tabs 14F, 14G and the cooperating openings 20, 28 in baseplate 10 and insert 12 described above. See also ¶ [0054].

ii. Specific Language of Independent Claim 15 Including References to the Specification and Drawings

Claim 15. A device, comprising:

a first tibia base plate (10) comprising an upper surface, a lower surface and an outer perimeter side surface (33) extending between said upper surface and said lower surface of said first tibia base plate (Figures 10A, 10B, 10D) ¶ [0046];

an insert (12) comprising an upper surface, a lower surface and an outer perimeter side surface (31) extending between said upper surface and said lower surface of said insert (Figures 10A-10B), said insert adapted to be positioned above said first base plate (Figure 10B), said insert (12) and said first base plate (10) having a first configuration, wherein said insert (12) is translationally fixed to said first base plate (10) and rotatable relative t

a means for rotatably connecting said insert to said first tibia base plate (22, 24, ¶ [0038]); and

a removable means for selective engagement with both said insert and said first tibia base plate for preventing relative rotation between said insert and said first base plate (14, 14F, 14G, 20, 28, ¶ [0054]), wherein, when installed, a first portion (14F) of said removable means is configured to engage an opening (20) formed in said outer perimeter side surface (33) of said first base plate (10) and a second portion (14G) of said removable means is configured to engage an opening formed in said outer perimeter side surface (31) of said insert (12) to thereby prevent relative rotation between said insert (12) and said first base plate (10) ¶ [0046].

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

In the Final Office Action dated December 23, 2010, the Examiner rejects claims 1-3, 6, 7, 10-12, 15, 16, 18, 19, 21, 22 and 24-26 under 35 U.S.C. §103(a) as being obvious over U.S. Patent No. 6,660,039 to Evans et al. (hereinafter "Evans") and U.S. Patent Application Publication No. 2004/0186584 to Keller (hereinafter "Keller"). The Examiner rejects claims 13, 14, 27 and 28 by relying further on secondary references.

The grounds of rejection to be reviewed on appeal are whether claims 1-3, 6, 7, 10-16, 18, 19, 21, 22, 24-28 are patentable over Evans and Keller.

VII. ARGUMENT

A. Summary of Prior Art

Evans

Evans discloses mobile bearing knee prosthesis 10, shown in Figure 1, that includes tray 13 and insert 28. Tray 13 includes post 18 extending upwardly therefrom that is configured for receipt within vertical channel 33 of insert 28. With post 18 of tray 13 positioned within vertical channel 33 of insert 28, insert 28 may be rotated and translated atop tray 13. Additionally, by inserting fastener 24 within vertical channel 33 and threadingly engaging the same to post 18 of tray 13, translations 28 relative to tray 13 are prevented while relative rotation continues to be allowed. In an alternative arrangement, as shown in Figures 18-25, post 18 may be replaced by interchangeable posts 42, 49, 53 and 59, which may be received within a recess and baseplate 13 and which are configured to extend into square opening 64 and insert 28. By interchanging posts 42, 49, 53 and 59, insert 28 may be configured for different combinations of rotation and

translation relative to tray 13 as shown by the arrows (or lack thereof) in Figures 22-25. Specifically, by interchanging posts 42, 49, 53 and 59, insert 28 may be configured to rotate but not translate, neither rotate nor translate, translate but not rotate or both rotate and translate, respectively, atop tray 13. Tray 13 is never rotatably connected to the insert (by post 18) and engageable by a post (49, 53) to prevent rotation, as posts 49, 53 are used in lieu of post 18, not together with post 18.

2. Keller

Keller discloses a knee prosthesis, as shown in Figure 1, including tibial component 1 and femoral component 3. Femoral component 3 is secured to tibial component 1 by pin stumps 12, 13 of tibial component 1, as shown in Figures 2 and 6. Specifically, pin stumps 12, 13 may be retracted to allow for femoral component 3 to be positioned atop tibial component 1. Then, pin stumps 2, 3 may be allowed to extend outwardly and into recesses in terminal component 3 to secure tibial component 1 and femoral component 3 together. To separate tibial component 1 and femoral component 2 shown in Figure 9 are inserted into openings 25 of tibial component 1 to retract pin stumps 12, 13.

B. Summary of Argument

In rejecting independent claims 1 and 15 together with the claims depending therefrom, the Examiner argues that Evans discloses the claimed tibial baseplate (13), an insert (28), a connector (18) rotatably connecting the insert to the baseplate and at least one removable pin (27). Keller is cited as disclosing a "pin located on the outer perimeter", with reference to paragraph 7 thereof. December 23, 2010 Office Action, page 3.

Appellants have interviewed the Examiner regarding this application on several occasions. During these interviews, Appellants explained to the Examiner that locking member 24¹ is not configured to prevent relative rotation between the insert and the first baseplate as called for in Appellants' independent claims 1 and 15. Responsive to this deficiency in the

¹While the Examiner's rejection identifies element 27 of Evans, which Evans identifies as a "tool receptive socket" as Appellants' claimed removable pin, Appellants believe that the Examiner intends to refer to "locking member 24" of Evans.

disclosure of Evans, the Examiner argues that the language of independent claims 1 and 15 "only describes the intended use of the pin." Office Action dated December 23, 2010, page 4, line 7. The Examiner goes on to argue that "the (claim) language does not positively claim any limitations that further describe the structure of the claimed device. Therefore it is maintained that the combination of Evans in view of Keller still reads on the claims as dependent Evans would be capable of being in contact with the periphery of the insert on the baseplate." Id. at lines 7-11.

Appellants respectfully disagree with the Examiner's indication that the claim language "only describe[s] the intended use of the (claimed) pin" and that the claim language "does not positively recite any limitations that further describe the structure of the claimed device." Id. at page 4. Independent claim 1 recites a first tibia baseplate, an insert having a first configuration in which the insert is translationally fixed to and rotatable relative to the baseplate, a connector rotatably connecting the insert to the baseplate and at least one removable pin having a first portion and a second portion, the first portion of the pin sized for engagement with an opening formed in an outer perimeter side surface of the baseplate and a second portion of the pin sized for engagement with an opening formed in the outer perimeter side surface of the insert to thereby prevent relative rotation between the insert and the first baseplate. This claim structurally recites an opening in the baseplate and an opening in the insert as well as a pin having portions sized for engagement with the openings in the baseplate and insert to thereby prevent relative rotation between the insert and the baseplate. It is the claimed sizing of these cooperating structures which brings about the prevention of relative rotation between the insert and the baseplate. While Appellants recitation of "at least one removeable pin" in claim 1 is. couched in part in functional language ("to thereby prevent relative rotation between the insert and the first baseplate"), it is well settled that "[a] patent applicant is free to recite features of an apparatus either structurally or functionally." In re Schreiber, 128 F.3d 1473, 1478 (Fed. Cir. 1997) (citing In re Swinehart, 439 F.2d 210, 212 (CCPA 1971) ("[T]here is nothing intrinsically wrong with [defining something by what it does rather than what it is] in drafting patent claims.")).

Contrary to the Examiner's assertion that the claim language "only describe[s] the intended use of the [claimed] pin" and that the claim language "does not positively recite any limitations that further describe the structure of the claimed device", Appellants respectfully submit that the claimed "removable pin" is limited structurally in several ways that define it over locking member 24 of Evans. Applicants claimed "removable pin" is not only sized for engagement with an opening in the first base plate and an opening in the insert, but it is so sized "to thereby prevent relative rotation between said insert and said first base plate." The structure of the pin/opening combinations is thus limited to those structures sized so that they would cooperate to "prevent relative rotation between said insert and said first base plate". Contrary to this claimed structure, the structure in Evans of locking member 24 and cylindrically-shaped section 34 of vertical channel 33 of insert 28 are specifically sized to allow rotation between insert 28 and tray 13. U.S. Patent No. 6,660,039, column 9, line 66 - column 10, line 44 ("The cylindrically-shaped head 26 of locking member 24 closely fits the cylindrically-shaped section 36 [of vertical channel 33].... In FIG. 16, the fastener 24 has been threadably attached to the internally threaded socket 19 and is in operating position. In FIG. 17, the insert 28 can rotate relative to the tray 13 through an angle 41. However, because of the attachment of fastener 24, only rotation and not translation is permitted in FIG.17.").

Because cylindrically-shaped head 26 of locking member 24 of Evans is not sized for engagement with an opening formed in insert 28 to thereby prevent relative rotation between insert 28 and tray 13, but rather is configured to *allow* rotation between insert 28 and tray 13, Appellants respectfully submit that the prior art cited by the Examiner does not meet the structure of the "removable pin" called for in Appellants' independent claim 1.

While Keller is cited only with regard to the location of its pins 12, 13, Appellants note that the pins of Keller are also sized to *allow* rotation between femoral component 3 and tibial component 1.

Independent claim 15 calls for a first tibia baseplate, an insert, means for rotatably connecting the insert to the tibia baseplate and removable means for selective engagement with both the insert and the tibia baseplate for preventing relative rotation between the insert and the

first baseplate. The MPEP dictates that "[a] claim limitation will be presumed to invoke 35 U.S.C. 112, sixth paragraph, if it meets the following 3-prong analysis: (A) the claim limitations must use the phrase 'means for' or 'step for,' (B) the 'means for' or 'step for' must be modified by functional language; and (C) the phrase 'means for' or 'step for' must not be modified by sufficient structure, material, or acts for achieving the specified function." MPEP Section 2181 I. Under this test, the recitation in claim 15 of "removable means for selective engagement with both said insert and said first tibia base plate for preventing relative rotation between said insert and said first base plate, wherein, when installed, a first portion of said removable means is configured to engage an opening formed in said outer perimeter side surface of said insert to thereby prevent relative rotation between said insert and said first base plate" should clearly be interpreted under 35 U.S.C. Section 112, paragraph 6 for the following reasons: (A) this claim limitation uses the phrase "means for"; (B) the "means for" language is modified by functional language ("selective engagement" and "preventing relative rotation between said insert and said first base plate") and (C) the phrase "means for" is not modified by sufficient structure, material or acts for performing the specified function (while claim 15 does include the recitation that the removable means includes a first portion configured to engage an opening formed in the outer perimeter side surface of the first base plate and a second portion configured to engage an opening formed in the outer perimeter side surface of the insert to thereby prevent relative rotation between said insert and said first base plate, no specific structure for performing the recited function of "preventing relative rotation between said insert and said first base plate" is provided).

A threshold question in considering the obviousness of a means plus function claim limitation is whether the proposed combination of the prior art meets the recited function identically. See MPEP § 2183. In this case, the recited function of "selective engagement with both said insert and said first tibia baseplate for preventing relative rotation between the insert and the baseplate" is clearly not met by Evans, as locking member 24 of Evans cooperates with an opening in insert 28 of Evans to allow rotation, not to prevent rotation as recited in the "means for" limitation of Appellant's independent claim 15. Without passing the threshold inquiry of whether identity of function can be found between the prior art combination proposed by the Examiner and Applicants means plus function claim limitation, the Examiner cannot proceed to

apply the remaining test for patentability, i.e., whether the prior art combination provides a structure identical or equivalent to the structure disclosed in the specification and associated with the recited means plus function element. MPEP § 2183.

Even if claim 15 were somehow interpreted to fall outside of the ambit of 35 U.S.C. Section 112 paragraph 6, the functional language of claim 15 would limit the claim in a way similar to claim 1 argued above. In short, functional language can be used to limit a claim whether 35 U.S.C. Section 112 paragraph 6 is invoked or not and such language cannot be ignored in the evaluation of the patentability of claims including such language. Therefore, the Examiner's rejection of independent claims 1 and 15 as well as claims 2, 3, 6, 7, 10-14, 16, 18, 19, 21, 22 and 24-28 depending therefrom should be overturned.

VIII. CONCLUSION

In view of the above, Appellant respectfully submits that the present application is in order for allowance and respectfully requests the Board to direct the Examiner to withdraw the Final Office Action and issue a Notice of Allowance.

In the event that Appellants have overlooked the need for an extension of time or a payment of an additional fee, Appellants hereby petition therefor and authorize that any charges be made to Deposit Account No. 02-0385, Baker & Daniels LLP.

Respectfully submitted,

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IX. CLAIMS APPENDIX

(Rejected): A device, comprising:

a first tibia base plate comprising an upper surface, a lower surface and an outer perimeter side surface extending between said upper surface and said lower surface of said first tibia base plate;

an insert comprising an upper surface, a lower surface and an outer perimeter side surface extending between said upper surface and said lower surface of said insert, said insert adapted to be positioned above said first base plate, said insert and said first base plate having a first configuration, wherein said insert is translationally fixed to said first base plate and rotatable relative to said first base plate:

a connector rotatably connecting said insert to said first tibia base plate; and

at least one removable pin having a first portion and a second portion, said first portion of
said pin sized for engagement with an opening formed in said outer perimeter side surface of said
first base plate and said second portion of said pin sized for engagement with an opening formed
in said outer perimeter side surface of said insert to thereby prevent relative rotation between
said insert and said first base plate.

- (Rejected): The device of claim 1, wherein said first base plate is comprised of a metal.
- (Rejected): The device of claim 1, wherein said insert is comprised of a nonmetallic material.

4-5. (Canceled)

6. (Rejected): The device of claim 1, wherein at least a portion of said pin is secured in an opening in said first base plate by at least one of a press-fit connection, a threaded connection, and a sintered connection.

 (Rejected): The device of claim 1, wherein said pin has an outer surface that is substantially flush with said outer perimeter side surface of one of said first base plate and said insert.

8-9. (Canceled)

10. (Rejected): The device of claim 1, wherein said openings in said first tibia base plate and said insert are formed on anterior portions of said outer perimeter side surfaces of said first base plate and said insert, respectively.

- (Rejected): The device of claim 1, wherein said pin has at least one of a circular, rectangular and square cross-sectional configuration.
- 12. (Rejected): The device of claim 1, wherein said pin has a smooth exterior surface.
- (Rejected): The device of claim 1, wherein said pin has at least one projection formed on an exterior surface of said pin.

- 14. (Rejected): The device of claim 1, wherein said pin is comprised of a metal.
- 15. (Rejected): A device, comprising:

a first tibia base plate comprising an upper surface, a lower surface and an outer perimeter side surface extending between said upper surface and said lower surface of said first tibia base plate;

an insert comprising an upper surface, a lower surface and an outer perimeter side surface extending between said upper surface and said lower surface of said insert, said insert adapted to be positioned above said first base plate, said insert and said first base plate having a first configuration, wherein said insert is translationally fixed to said first base plate and rotatable relative to said first base plate;

a means for rotatably connecting said insert to said first tibia base plate; and
a removable means for selective engagement with both said insert and said first tibia base
plate for preventing relative rotation between said insert and said first base plate, wherein, when
installed, a first portion of said removable means is configured to engage an opening formed in
said outer perimeter side surface of said first base plate and a second portion of said removable
means is configured to engage an opening formed in said outer perimeter side surface of said
insert to thereby prevent relative rotation between said insert and said first base plate.

16. (Rejected): The device of claim 15, wherein said removable means for preventing relative rotation between said insert and said first base plate comprises a removable pin.

17. (Canceled)

18. (Rejected): The device of claim 15, wherein said first base plate is comprised of a metal.

 (Rejected): The device of claim 15, wherein said insert is comprised of a nonmetallic material.

20. (Canceled)

21. (Rejected): The device of claim 15, wherein said removable means for preventing relative rotation between said insert and said first base plate has an outer surface that is substantially flush with said outer perimeter side surface of one of said first base plate and said insert.

22. (Rejected): The device of claim 15, wherein at least a portion of said removable means for preventing relative rotation between said insert and said first base plate is secured in an opening in said first base plate by at least one of a press-fit connection, a threaded connection, and a sintered connection.

(Canceled)

24. (Rejected): The device of claim 15, wherein said openings in said first tibia base plate

and said insert are formed on anterior portions of said outer perimeter side surfaces of said first

base plate and said insert, respectively.

25. (Rejected): The device of claim 15, wherein said removable means for preventing

relative rotation between said insert and said first base plate has at least one of a circular,

rectangular and square cross-sectional configuration.

26. (Rejected): The device of claim 15, wherein said removable means for preventing

relative rotation between said insert and said first base plate has a smooth exterior surface.

27. (Rejected): The device of claim 15, wherein said removable means for preventing

relative rotation between said insert and said first base plate has at least one projection formed on

an exterior surface of said removable means.

28. (Rejected): The device of claim 15, wherein said removable means for preventing

relative rotation between said insert and said first base plate is comprised of a metal.

29-42. (Canceled)

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X. EVIDENCE APPENDIX

None.

XI. RELATED PROCEEDINGS APPENDIX

None.